UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,191	10/22/2003	Pamela Cifra	020154-001110US	8424

7590 12/06/2005

Ken Sonnenfeld, Esq
Morgan & Finnegan LLP
345 Park Avenue
New York, NY 10154

EXAMINER	
ROYDS, LESLIE A	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 12/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/692,191	CIFRA ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-98 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-98 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-98 are presented for examination.

Requirement for Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2-12, drawn to a method for increasing fatty tissue comprising administering to a subject a composition of zinc-containing components, classified in class 424, subclasses 401 and 642, for example.

II. Claims 13-23, drawn to a method for decreasing fatty tissue comprising administering to a subject a composition of zinc-containing components, classified in class 424, subclasses 401 and 642, for example.

III. Claims 24-35 and 68-75, drawn to a method for increasing elastin content in a tissue or in the eye, comprising application of a composition of zinc-containing components topically or via placement of a contact lens in the eye, classified in class 424, subclasses 401 and 642, for example.

IV. Claims 36-46, drawn to a method for increasing epidermal thickness comprising the administration of a composition of zinc-containing components, classified in class 424, subclasses 401 and 642, for example.

V. Claims 47-57, drawn to a method for decreasing epidermal thickness comprising the administration of a composition of zinc-containing components, classified in class 424, subclasses 401 and 642, for example.

VI. Claims 58-67, drawn to a method for treating gums comprising the topical application of a composition of zinc-containing components, classified in class 424, subclasses 401 and 642, for example.

VII. Claims 76-98, drawn to a composition of zinc-containing components and a contact lens formulation thereof, classified in class 424, subclasses 401 and 642, for example.

Claim 1 links Inventions I through VI. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim (i.e., claim 1). Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicant is advised that if any such claims depending from or including all the limitations of the allowable linking claim is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP §804.01.

The inventions are distinct, each from the other, for the following reasons:

Inventions VII and Inventions I-VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (MPEP § 806.05(h)). In the instant case, the composition of zinc-containing components, may also be used in a materially different process of using such compounds. In particular, such a composition may be used for supplementation of a subject's daily intake of zinc, particularly for augmenting immune function; increasing absorption of zinc in vegetarians who have reduced absorption of zinc from plant foods alone; and for the replacement of zinc lost during the course of acute digestive disorders, such as diarrhea, Crohn's disease or short bowel syndrome.

Inventions I through VI are patentably distinct. Inventions are patentably distinct if it can be shown that they have different modes of operation, different functions, or different effects and different resultant endpoints (See MPEP § 806.04, MPEP § 808.01). In the instant case, it is noted that the ultimate therapeutic objective of, for example, Invention I (i.e., increasing fatty tissue in or beneath the skin of a subject) is distinct from the therapeutic objective of, for example, Invention II (i.e., decreasing fatty tissue in or beneath the skin of a subject), of which each is distinct from each one of the therapeutic objectives of Inventions III, IV, V or VI.

Inventions I through VI are held to be patentably distinct because the treatment of any one of Inventions I through VI would not necessarily result in the treatment of the other invention. The patient populations in which each method would be practiced are distinctly different (e.g., patients requiring an increase in the amount of fatty tissue in or beneath the skin versus patients requiring a decrease in the amount of fatty tissue in or beneath the skin), such that the treatment of one patient population would not necessarily suggest, anticipate or render obvious the treatment of the other patient population. While there may be incidental overlap in the groups of patients experiencing, for example, a need for increased fatty tissue in certain

anatomical locations and those experiencing, for example, a need for decreased fatty tissue in other anatomical locations, the therapeutic objectives, endpoints and steps required to treat such conditions are vastly different and do not reasonably suggest, anticipate or render obvious the treatment of the other.

Furthermore, the dosage amounts or frequency and route of administration necessary to effect the treatment of patients with, for example, a need for increased fatty tissue, would necessarily be independent and distinct from that required for the treatment of patients with, for example, a need for decreased fatty tissue, due to the differences in etiology of such a condition and the activity of the claimed agent(s) in treating such a condition. Moreover, one skilled in the art could practice the invention of either I, II, III, IV, V or VI without practicing the invention of any one of the other inventions. Thus, Inventions I through VI are properly considered patentably distinct from one another.

Because these inventions are distinct for the reasons given above and the search required for any one of Groups I through VII is not required for any one of the other groups, the inventions are held to be distinct and restriction for examination purposes as indicated is proper.

Claims 6, 17, 29, 39, 51, 61 and 72 are generic to a plurality of disclosed patentably distinct species comprising the following zinc salts: (i) acetate; (ii) ascorbate; (iii) aspartate; (iv) butyrate; (v) caproate; (vi) caprylate; (vii) carbonate; (viii) chromate; (ix) citraconate; (x) citramalate; (xi) citrate; (xii) EDTA; (xiii) formate; (xiv) fumarate; (xv) gallate; (xvi) gluconate; (xvii) halides; (xviii) iodate; (xix) lactate; (xx) laurate; (xxi) laureate; (xxii) malate; (xxiii) maleate; (xxiv) malonate; (xxv) metaphosphate; (xxvi) methanesulfonate; (xxvii) monophosphate; (xxviii) myristate; (xxix) nitrate; (xxx) octoate; (xxxi) oleate; (xxxii) orotate;

(xxxiii) orthophosphate; (xxxiv) oxalate; (xxxv) oxides; (xxxvi) palmitate; (xxxvii) permanganate; (xxxviii) phenolsulfate; (xxxix) phosphate; (xxxx) picolinate; (xxxxi) propionate; (xxxxii) pyrophosphate; (xxxxiii) salicylate; (xxxxiv) selenate; (xxxxv) stearate; (xxxxvi) succinate; (xxxxvii) sulfate; (xxxxviii) sulfonate; (xxxxix) tannate; (xxxxx) tartrate; (xxxxxi) tetrametaphosphate; (xxxxxii) titanate; (xxxxxiii) transferring; (xxxxxiv) tripolyphosphate; (xxxxxv) undecylate; or (xxxxxvi) valerate. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call was made to Ken Sonnenfeld at Morgan & Finnegan, L.L.P. on Friday, December 02, 2005 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The Examiner has required restriction between product and process claims. Where Applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP §821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 C.F.R. 1.116; amendments submitted after allowance are governed by 37 C.F.R. 1.312.

I n the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. §103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicants are advised that the process claims should be amended during prosecution either to maintain

dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the Examiner withdraws the restriction requirement before the patent issues. See MPEP §804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (8:30 AM-6:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leslie A. Royds
Patent Examiner
Art Unit 1614

December 2, 2005

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600